

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
DEPARTMENT OF PESTICIDE REGULATION  
MEDICAL TOXICOLOGY BRANCH**

**SUMMARY OF TOXICOLOGY DATA  
*AGROBACTERIUM RADIOBACTER***

Chemical Code # 001984, DPN # 50136  
SB 950 # 245

Original date: January 3, 2002; revised April 12, 2005

**I. DATA GAP STATUS**

<b>Chronic toxicity, rat:</b>	Data gap, study not submitted
<b>Chronic toxicity, dog:</b>	Data gap, study not submitted
<b>Oncogenicity, rat:</b>	Data gap, study not submitted
<b>Oncogenicity, mouse:</b>	Data gap, study not submitted
<b>Reproduction, rat:</b>	Data gap, study not submitted
<b>Teratology, rat:</b>	Data gap, study not submitted
<b>Teratology, rabbit:</b>	Data gap, study not submitted
<b>Gene mutation:</b>	Data gap, study inadequate, no adverse effect indicated
<b>Chromosome effects:</b>	Data gap, study not submitted
<b>DNA damage:</b>	Data gap, study not submitted
<b>Neurotoxicity:</b>	Not required at this time

---

Toxicology one-liners are attached.

All record numbers through 117069 were examined.

\*\* indicates an acceptable study.

**Bold face** indicates a possible adverse effect.

File name: T020103 prepared by J. Gee; revised by Gee, April 12, 2005.

*Agrobacterium radiobacter* is a biopesticide used on nursery stock to prevent crown gall, caused by a related bacterium, *Agrobacterium tumefaciens*. In June, 1995, US EPA published a Reregistration Eligibility Document, presenting mammalian and human toxicity and exposure potential. At that time, the EPA was requiring no further toxicity testing beyond the acute studies on file. See below.

NOTE: In a memorandum dated June 23, 2003, the Office of Environmental Health Hazard Assessment (OEHHHA) concurred with the Department of Pesticide Regulation that no further studies were required at this time for the registered strain(s) of *Agrobacterium radiobacter*. (Gee,

4/12/05)

## II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

### COMBINED, RAT

No study submitted

### CHRONIC TOXICITY, RAT

No study submitted

### CHRONIC TOXICITY, DOG

No study submitted

### ONCOGENICITY, RAT

No study submitted

### ONCOGENICITY, MOUSE

No study submitted

### REPRODUCTION, RAT

No study submitted

### TERATOLOGY, RAT

No study submitted

### TERATOLOGY, RABBIT

No study submitted

### GENE MUTATION

008 045325 Moore, L. W., K. Tindall, G. Warren and M. Staver. "Investigation of *Agrobacterium radiobacter* Strain K84 and an Antibiotic it Produces (Agrocin 84) for Mutagenic Activity". (Oregon State U and Montana State U., 1979) *Agrobacterium radiobacter* and the antibiotic it produces were tested for mutagenicity using *Salmonella typhimurium* tester strains TA 1535, TA98 and TA 100, with and without rat-liver activation. The test material was applied as a "spot" on the plates (duplicate plates, three methods). The agrocin migrated through the agar. Results were scored as "++" or "-", rather than by colony count. Positive controls were reported as "++". No evidence of mutagenicity with *A. radiobacter* or agrocin. UNACCEPTABLE (Insufficient information), not upgradeable. (Kishiyama and Gee, 1/2/2002).

### CHROMOSOME EFFECTS

No study submitted

### DNA DAMAGE

No study submitted

## MISCELLANEOUS

### Acute:

011 117069 Baltezare, M. "Rabbit Eye Irritation". (Unilab Research, Laboratory Number 9861 and 10056, May 25, 1975.) One-tenth of a ml of Galltrol - A [*A. radiobacter* culture, not described] was applied to one eye of each of the 6 New Zealand rabbits. Eye effects of the cornea in unwashed eyes was prolonged to 21 days for 1 rabbit, grade 1; therefore, a repeat study was performed on 4 rabbits. Eye irritation of the cornea was grade 1 in 1/4 at 24 hours but not present at 48 hours post treatment in the repeat study. Washed eyes of 3 rabbits showed grade 1 corneal affects at 24 hours only. Category III. UNACCEPTABLE, upgradeable with description of the test article. (Kishiyama and Gee, 1/2/02).

011 117069 Baltezare, M. "Rabbit Skin Irritation". (Unilab Research, Laboratory Number 9861, May 25, 1975.) 0.5 gram of Galltrol - A [*A. radiobacter* culture] was applied once dermally for a 24 hour period to intact and abraded skin to determine the extent of skin irritation using 6 albino rabbits. The material was applied under gauze but no mention was made about moistening. The severity of erythema and edema was slight and not persistent for 7 days. The test article, therefore, was considered not a skin irritant. Category IV. UNACCEPTABLE (Kishiyama and Gee, 1/2/02).

011 117029 Phillips, D. "Acute Oral Infectivity Test" (Northview Pacific Laboratory, Number X2K011, January 17, 1983.) Galltrol A (*Agrobacterium radiobacter* [Strain 84]  $1.2 \times 10^8$  /ml) at a dose of 5g/kg live cells (20 ml/kg) or killed cells (control) was administered orally to 5 or 2 Sprague-Dawley rats/sex, respectively. All rats showed signs of pulmonary edema, including those exposed to killed organisms. The study director stated this condition was "not unusual" for this population of animals, obtained from a "reliable" source. No other abnormalities reported in animals observed for 14 days. No deaths occurred. Clearance was not measured. Category IV. ACCEPTABLE. (Kishiyama and Gee, 1/3/02).